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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/967,238	09/27/2001	Rongdian Fu	55525-8049.US00	6602

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EXAMINER

LU, FRANK WEI MIN

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 05/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/967,238

Applicant(s)

FU ET AL.

Examiner

Frank W Lu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1/23/2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 18-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 and 26-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 September 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. Applicant's response to the office action filed on January 23, 2004 has been entered. The claims pending in this application are claims 1-28 wherein claims 18-25 have been withdrawn from consideration due to the restriction requirement. Rejection and/or objection not reiterated from the previous office action are hereby withdrawn in view of the amendment filed on January 23, 2004.

Information Disclosure Statement

2. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered. Note that applicant does not address this issue.

Claim Objections

3. Claim 1 is objected to because of the following informalities: (1) "contacting with a reference library which comprises multiple copies of a selected nucleic acid sequence" in step (a) should be "contacting a reference library which comprises multiple copies of a selected nucleic acid sequence with"; and (2) "said SID sequences are present as single stranded extensions on

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said duplexes" should be "said SID sequences are present as single stranded extensions in said duplexes".

4. Claim 1 is objected to because of the following informalities: (1) "contacting with a reference library which comprises the nucleic acid sequences present in the nucleic acid populations" should be "contacting a reference library which comprises the nucleic acid sequences present in the nucleic acid populations with"; (2) "said SID sequences are present as single stranded extensions on said duplexes" should be "said SID sequences are present as single stranded extensions in said duplexes"; and (3) "exclusive of the SID sequence" should be "exclusive of the first and second SID sequences".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-17 and 26-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claims 1 and 26 are rejected as vague and indefinite because it is unclear what means "the ratio of said first and second probes forming duplexes with said selected sequence". Does this phrase mean that the ratio of the amount of said first probe in a complex formed by said first probe and said selected sequence to the amount of said second probe in a complex formed by said second probe? Please clarify.

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8. Claim 1 is rejected as vague and indefinite. Since, from the first part of contacting step, the selected sequence is not part of the first nucleic acid population or the second nucleic acid population, it is unclear what means that "the ratio of the amount of the selected sequence in the first nucleic acid population to the amount of the selected sequence in the second nucleic acid" as recited in the second part of contacting step. Therefore, the first part and the second part of contacting step do not correspond each other. Please clarify.

9. Claims 1 and 26 are rejected as vague and indefinite. According to contacting step, "SID" can mean a terminal first sample ID sequence or a terminal second sample ID sequence, it is unclear how "SID" can have two different meanings. Please clarify.

10. Claims 1 and 26 are rejected as vague and indefinite because it is unclear that "said SID sequences" means a terminal first sample ID sequence or a terminal second sample ID sequence. Please clarify.

11. Claim 1 is rejected as vague and indefinite because it is unclear that "unhybridized SID sequences" in step (b) means a terminal first sample ID sequence or a terminal second sample ID sequence. Please clarify.

12. Claim 2 recites the limitation "a plurality of different-sequence probes derived from said first nucleic acid population" in the claim. There is insufficient antecedent basis for this limitation in the claim because claim 1 does not indicate that said first nucleic acid population has a plurality of different-sequence probes. Please clarify.

13. Claim 2 recites the limitation "a plurality of different-sequence probes derived from said second nucleic acid population" in the claim. There is insufficient antecedent basis for this

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limitation in the claim because claim 1 does not indicate that said second nucleic acid population has a plurality of different-sequence probes. Please clarify.

14. Claim 2 recites the limitation "said reference library comprises multiple copies of the different sequences present in the first and second nucleic acid populations" in the claim. There is insufficient antecedent basis for this limitation in the claim because claim 1 does not indicate that said reference library comprises multiple copies of the different sequences present in the first and second nucleic acid populations. Please clarify.

15. Claim 2 is rejected as vague and indefinite in view of the phrase "different sequences within the library are attached to spatially distinct solid phase supports in clonal subpopulations" because it is unclear that "different sequence" in this phrase means different sequence from the first nucleic acid population or means different sequence from the second nucleic acid population or means different sequence from the reference library. Please clarify.

16. Claim 5 recites the limitation "each said unhybridized SID sequence" in the phrase. There is insufficient antecedent basis for this limitation in the claim since there is no phrase "each said unhybridized SID sequence" in claims 1 and 2. Please clarify.

17. Claim 6 recites the limitations "unhybridized first SID sequence" and "unhybridized second SID sequence". There is insufficient antecedent basis for this limitation in the claim since there are no phrases "unhybridized first SID sequence" and "second unhybridized SID sequence" in claims 1, 2, and 5. Please clarify.

18. Claim 6 recites the limitations "first decoder moieties" and "second decoder moieties". There is insufficient antecedent basis for this limitation in the claim since there are no phrases "first decoder moieties" and "second decoder moieties" in claims 1, 2, and 5. Please clarify.

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19. Claim 7 recites the limitations "each said decoder moieties". There is insufficient antecedent basis for this limitation in the claim since there is no phrase "each said decoder moieties" in claims 1, 2, 5, and 6. Please clarify.

20. Claim 8 recites the limitations "said labeled decoder moieties". There is insufficient antecedent basis for this limitation in the claim since "said labeled decoder moieties" recited in claim 8 is not equal to "a labeled decoder moiety". Please clarify.

21. Claim 9 recites the limitations "said each said decoder label". There is insufficient antecedent basis for this limitation in the claim since there is no phrase "each decoder label" in claims 1, 2, 5, and 8. Please clarify.

22. Claim 10 recites the limitations "said fluorescent labels". There is insufficient antecedent basis for this limitation in the claim since there is no phrase "fluorescent labels" in claims 1, 2, 5, and 8. Please clarify.

23. Claim 11 recites the limitations "said ratio of fluorescent signal". There is insufficient antecedent basis for this limitation in the claim since there is no phrase "ratio of fluorescent signals" in claims 1, 2, 5, 8, and 10. Please clarify.

24. Claim 16 recites the limitations "each of a plurality of sources". There is insufficient antecedent basis for this limitation in the claim since there is no phrase "each of a plurality of sources" in claims 1 and 2. Please clarify.

25. Claim 17 is rejected as vague and indefinite because it is unclear that "such individuals" mean different individuals or not. Please clarify.

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26. Claim 26 is rejected as vague and indefinite because it is unclear that "the nucleic acid populations" means the first nucleic acid population or means the second nucleic acid population or means the first and second nucleic acid populations. Please clarify.

27. Claim 26 is rejected as vague and indefinite because it is unclear what sequence in said first and second probes can be considered as "the same sequence". Please clarify.

28. Claim 26 is rejected as vague and indefinite because it is unclear that "said first and second probes having the same sequence" is identical to "said first and second probes having a given sequence and forming duplexes with a complementary reference sequence" or not since, from plain meanings, "said first and second probes having the same sequence" and "said first and second probes having a given sequence and forming duplexes with a complementary reference sequence" are not considered to be identical. Please clarify.

29. Claim 26 is rejected as vague and indefinite because it is unclear that "the complement of said same sequence" is identical to "the complementary sequence" or not since, from plain meanings, "the complement of said same sequence" and "the complementary sequence" are not considered to be identical. Please clarify.

30. Claim 26 recites the limitation "each unhybridized SID sequence" in step (b) of the claim. There is insufficient antecedent basis for this limitation in the claim because there is no unhybridized SID sequence in step (a) of the claim. Please clarify.

31. Claim 26 recites the limitation "a first fluorescent label", "first decoder moieties", "a second, distinguishable fluorescent label", and "second decoder moieties" in step (b) of the claim. There is insufficient antecedent basis for this limitation in the claim because step (b) only

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indicates that each unhybridized SID sequence has a decoder moiety having a fluorescent label.

Please clarify.

32. Claim 26 recites the limitation "said fluorescent labels on each microparticle" in step (b) of the claim. There is insufficient antecedent basis for this limitation in the claim because steps (a) and (b) do not indicate that each microparticle has a fluorescent label. Please clarify.

33. Claim 27 recites the limitation "each said decoder moiety" of the claim. There is insufficient antecedent basis for this limitation in the claim because there is no phrase "each decoder moiety" in claim 26. Please clarify.

34. Claim 28 is rejected as vague and indefinite. Since a decoder moiety of claim 26 has a fluorescent label while decoder moiety of claim 28 requires multiple fluorescent molecules. Therefore, claim 26 and claim 28 do not correspond each other and claim 28 lacks antecedent basis. Please clarify.

Response to Arguments

35. Applicant's arguments with respect to claims 1-17 and 26-28 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

36. No claim is allowed.

37. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG

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94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is either (703)872-9306 or (703)305-3014.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746.

The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (571)272-0782.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

Frank Lu
PSA
May 10, 2004


FRANK LU
PATENT EXAMINER